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## Background Paper

# Patient safety improvement programmes for primary care. Review of a Delphi procedure and pilot studies by the LINNEAUS collaboration on patient safety in primary care

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### KEY MESSAGE:

- Patient safety programmes in primary care have to deal with the specific characteristics of primary care.
- Engaging health professionals in patient safety programmes is crucial if we are to see improvements in patient safety.
- Prospective risk analysis (PRA) is useful as an innovative patient safety improvement programme.

### ABSTRACT

**Background:** To improve patient safety it is necessary to identify the causes of patient safety incidents, devise solutions and measure the (cost-) effectiveness of improvement efforts.

**Objective:** This paper provides a broad overview with practical guidance on how to improve patient safety.

**Methods:** We used modified online Delphi procedures to reach consensus on methods to improve patient safety and to identify important features of patient safety management in primary care. Two pilot studies were carried out to assess the value of prospective risk analysis (PRA), as a means of identifying the causes of a patient safety incident.

**Results:** A range of different methods can be used to improve patient safety but they have to be contextually specific. Practice organization, culture, diagnostic errors and medication safety were found to be important domains for further improvement. Improvement strategies for patient safety could benefit from insights gained from research on implementation of evidence-based practice. Patient involvement and prospective risk analysis are two promising and innovative strategies for improving patient safety in primary care.

**Conclusion:** A range of methods is available to improve patient safety, but there is no 'magic bullet.' Besides better use of the available methods, it is important to use new and potentially more effective strategies, such as prospective risk analysis.

**Keywords:** Patient safety, improvement, prospective risk analysis, LINNEAUS collaboration

### INTRODUCTION

Patient safety is a fundamental requirement in healthcare delivery (1–4). To improve patient safety systematically, we must identify the causes of patient safety incidents, devise solutions, and measure their impact. Improving patient safety is obviously the next logical step after analysis of safety problems, assuming that risks can be reduced in at least some clinical or organizational domains. In primary care, improvement strategies may

be guided by an analysis of identified incidents or they may target specific high-risk domains, such as medication safety or timely diagnosis of serious diseases (3,4). Patient safety programmes have to deal with specific characteristics of primary care, including the high yearly numbers of patients and contacts, the overall low risk of harm, and the broad diversity of conditions and procedures (4). In this paper, we will provide a broad overview with practical guidance on how to improve patient safety

in the primary care setting. The challenge for practitioners is to improve patient safety, avoiding unnecessary interventions and treatments associated with defensive medicine or excessive bureaucratic and administrative procedures.

In this paper, we describe results of two modified online Delphi approaches to achieve consensus on the most effective strategies to improve patient safety.

## METHODS

The Delphi panel included an international panel of primary care physicians, researchers with an interest in patient safety and policy makers. The methodology has been described in detail elsewhere (5). The content of the questionnaire used in this Delphi procedure was based on earlier studies exploring patient safety in primary care. In addition, five telephone interviews with international patient safety experts were conducted to further develop this questionnaire.

A set of the most salient points was then selected and put into a questionnaire, which was subsequently reviewed by three experts on patient safety in order to fine-tune the questions. Based on their opinion, the web-based survey instrument consisted of five themes: practice facilities, patient safety management, communication and collaboration, generic conditions for patient safety, and education on patient safety.

A panel was recruited in eight countries with relatively strong primary care systems: Austria, Denmark, France, Germany, the Netherlands, New Zealand, Slovenia and the UK (6). In each country of the LINNEAUS collaboration, we identified a key person and asked them to provide us with the names of 10 practising primary care physicians with a potential interest in patient safety and 10 researchers or experts in patient safety in their country.

We then sought the panel's views on 38 patient safety improvement strategies e.g. incident reporting, medication alerts, patient safety indicators, periodic medication review, training on patient safety and patient safety culture. For each strategy, we inquired about current usage in their country and whether the strategy, in their opinion, constituted a promising approach.

A second web-based survey was undertaken with the same panel. They were asked to rate 52 patient safety items regarding practice organization on a five-point Likert scale and assessing the importance of each item for its usefulness in educational interventions to improve patient safety (7).

Finally, for the LINNEAUS collaboration we performed two pilot studies of an innovative strategy, prospective risk analysis (PRA), as a means of assessing its utility in the primary care setting. The PRA focused on how to manage hygiene in daily GP practice and on the authorization process at a GP cooperative.

## RESULTS

### *What to improve?*

To improve patient safety, it is crucial to have insight into the prevalence and causes of patient safety incidents, devise approaches to improve patient safety, and measure the success of improvement efforts. The research literature shows that many different aspects of primary care are associated with patient safety incidents. For instance, a Canadian study identified six main areas where patient safety incidents were a problem: administration, communication, diagnosis, documentation, medication, and procedures (8). Another study of reported patient safety incidents showed the following risk factors: recall and reminder systems, knowledge and skills errors, errors related to medical records, communication between hospital and primary care, and management of medical emergencies (9). The research evidence also identified that in many cases a patient safety incident consists of a string of mistakes or unfavourable situations suggesting that many patient safety incidents have more than one cause (10).

Our literature reviews also showed that patient safety programmes can focus on a range of clinical and organizational domains. For example: good practice facilities, adequate safety management, improving patient safety culture or education. In our two modified Delphi procedures, the following three domains were identified as being the most important areas for focusing on improvement strategies.

### *Practice organization, safety management and culture.*

A literature review focusing on patient safety identified 23 major topics where patient safety was a problem (11). Organizational problems contributing to patient safety problems include poor teamwork, suboptimal handover of patients, and inadequate use of electronic patient records. However, it is still not clear if systems to address deficiencies in these areas can improve the healthcare for an individual patient (12). Remarkably, our second web survey concluded that hygienic procedures were the most important item, concerning what to improve for patient safety: in this regard, the use of sterile equipment with minor surgical procedures, regular cleaning of facilities and the use of sterile surgical gloves were highlighted (7).

There is some evidence that culture in organizations may be a relevant factor in healthcare performance, yet articulating and measuring the nature of that relationship has proved to be difficult (13). There is clear evidence that it is difficult to engage primary care workers in addressing cultural aspects of patient safety (13).

*Diagnostic errors.* Most serious patient safety events are seen with diagnostic delay or failure, in serious diseases

such as cancer, myocardial infarction, or other cardiovascular diseases (14). Diagnostic error, including avoidable delays and poor follow-up on tests, constitute an important category of patient safety incidents in general practice. Health problems in primary care can be complex and unpredictable. The challenge is to maintain the holistic and person-orientated view that characterizes much of general practice, and at the same time reduce the number of missed or wrong diagnoses. Problems underlying diagnostic error include complacency regarding common symptoms, which can mask complaints that are more serious, a lack of specialized knowledge of rare symptoms or diseases, and forgetting specific screening procedures (15). To reduce diagnostic errors, decision-support technology can help to optimize the use of diagnostic tests in clinical practice. For policy makers these systems can be important tools in reducing costs while at the same time improving patient safety. However, in implementing these systems it is important to evaluate the impact on adverse events, the impact on workflow, satisfaction of professionals and on costs and benefits.

*Medication errors.* Medication errors have been identified as major threats to patient safety in primary care, which result in many avoidable hospital admissions. Clinical computer systems with patient safety features could help, but the challenge is to overcome the problem that physicians often do not read these warnings (16). Polypharmacy is one of the factors behind the high rate of medication-related patient safety incidents, mostly affecting the elderly (17). Medication reviews and enhanced roles of pharmacists are potential strategies to reduce medication errors.

#### *How to improve?*

A widely shared view among experts of quality improvement is that strategies need to be tailored to barriers and facilitators of change. Insight into these factors is often based on interviews, surveys, and theoretical reflections. Theories may help to broaden the scope of ideas, although many theories are not well tested in healthcare settings. Most improvement strategies focus either on practitioners or on organizations.

Individual professionals need to be informed, motivated and perhaps trained to incorporate prevailing evidence regarding patient safety into their daily work. Empirical data show that lack of awareness and motivation, as well as perceived external factors, remains important barriers to adopting recommended practice. Educational programmes regarding patient safety for GPs have been developed in some countries, such as the Netherlands and the UK.

Healthcare professionals work in specific social, organizational and structural settings involving factors at

different levels that may support or impede change. Systematic reviews of studies on effective implementation of evidence and guidelines have shown that strategies that take into account different types of determinants of change are the most successful (18,19). Many studies have shown that failure to implement evidence involves factors at different levels of the healthcare system, including characteristics of professionals and patients; team functioning; influence of colleagues; organization of care processes; available time, staff and resources; policymaking and leadership. Structured approaches to planning for change have been developed in various scientific disciplines and they include mapping of interventions, marketing, small-group quality improvement, management of change, organizational development, and assessment of technology used in health care (19). Whether these structured approaches result in better uptake of knowledge and which of their components are most relevant remain unproven.

Our first modified Delphi consensus procedure in the LINNEAUS working group identified the following important strategies to improve patient safety in primary care. Although the majority of the 38 presented strategies were seen as important by most of the participants, the use of those strategies in daily practice varied widely (5). Hereunder we discuss the three most important improvement strategies. Table 1 provides an overview of relevant domains in primary care, potential determinants of errors, and potential safety improvement interventions.

*Incident reporting and analysis.* Incident reporting is probably the most researched strategy in the field of patient safety and has been promoted as one of the best methods to improve patient safety, although rigorous evaluations of the effectiveness of significant event analysis (SEA) are lacking (20–24). Most reported incidents were related to medication, management and diagnosis. A taxonomy showed that incidents in the process of healthcare were more common than those relating to deficiencies in the knowledge and skills of health professionals (9). An issue that it is often very difficult to judge is whether an incident was preventable (15). Significant event analysis is based on identifying incidents, and has been widely studied and is established as a tool for improvement in several European countries.

*The role of the patient.* Patients can play an important role in improving their own safety by becoming actively involved in their health care. When patients are allowed to review their own medical records, they may come across incidents (25). There is some evidence showing that patients observe errors in their diagnostic and treatment care in the ambulatory setting (26). Therefore, although patient-centeredness is a key feature of primary care, it is surprising that patient involvement has not

Table 1. Patient safety: Determinants and possible interventions on patient safety.

Risk areas (examples)	Determinants (examples)	Interventions (examples)
Missed diagnoses	Poor access to primary care Incompetent providers Inappropriate acceptance of symptoms	Improving telephone triage Decision support systems Patient education
Treatment risks	Incompetent providers Inadequate patient records Poor interprofessional communication	Incident reporting Prospective risk analysis Decision support systems Pharmacist involvement Shared patient records
Inadequate monitoring of patients	Inadequate patient records Inadequate practice organization	Incident reporting Prospective risk analysis Reminder systems
Hygiene risks	Absence of preventive measures Vulnerable patients	Restructuring of clinical process Incident reporting Prospective risk analysis Use of preventive measures Active patient involvement
		Incident reporting Prospective risk analysis

been translated into an explicit intervention in relation to patient safety programmes. Although patients cannot be held responsible for patient safety, they can make valid reports on adverse events and play a role in some aspects of the planning and delivery of their healthcare (8,27). There is currently a lack of empirical data on the extent to which patients could take on such a role (28). Interviews with patients suggest that poor communication with clinicians may be an important explanation for medical errors, suggesting that getting patient involvement in improving patient safety may be problematic (29).

*Prospective risk analysis.* Retrospective analytic methods to improve patient safety have been the mainstay of interventions to learn from errors. However, prospective risk analysis (PRA) is a method derived from the industry and could be useful as an innovative patient safety improvement programme but currently is not widely used in primary care (30). PRA is a five-step process, which uses a multidisciplinary team to evaluate proactively a healthcare process. This method works by first looking at the process, then at the possible problems and finally thinking about solutions. Practically there are several stages to using PRA. First, the patient safety topic has to be defined and then a multidisciplinary team with GPs and staff who play a role in this safety topic is assembled. Mostly, the team needs two to four meetings per topic. Usually, the team starts describing the process, ideally using a flow diagram. It is important to identify all sub-processes when the process is complex. After describing the process, the team uses process flow diagramming, a hazard scoring matrix, and a decision tree to identify and assess potential vulnerabilities. The team lists all possible

and potential failure modes for each of the processes and determines the severity and probability of the potential failure mode. A decision tree is used to determine whether the failure mode warrants further action. Next, the team determines whether to eliminate, control or to accept the failure mode causes. Finally, actions are described for each failure mode cause that will be eliminated or controlled. In this way, the vulnerabilities are not only judged by the likelihood of occurrence but also by the potential severity and the ease with which they might be detected and intercepted before causing harm.

The value of PRA is its preventative function allowing the practice to identify areas for intervention from established high-risk processes. In LINNEAUS, we studied the possibilities of this method for learning for patient safety and we defined areas where this method could be assessed (7). Areas that would benefit from this approach are, for instance, repeat prescriptions, telephonic triage and hygiene in the practice. The logical next step is to develop and evaluate tools enhancing patient safety in primary care that address these items.

We describe two examples in Boxes 1 and 2 of the use of PRA in our practice (on the role of the practice nurse in small surgical procedures and on the authorization process at a GP cooperative, respectively). Although these pilots showed that PRA is feasible in primary care, we recognize that it requires time and that the effects have yet to be examined in rigorous evaluations.

## DISCUSSION

Engaging health professionals in patient safety programmes poses challenges, but is crucial for their impact.



Box 1. Prospective risk analysis (PRA) on small surgical procedures in GP practice.

A pilot study was done to test PRA in primary care, focusing on the role of the practice nurse in small surgical procedures. Small surgical procedures are considered to be a high-risk process in primary care. The pilot took place in a group practice in a rural area with four GPs caring for approximately 7600 patients.

In the first meeting, a GP, a practice nurse and the moderator defined the problem. Some GPs in the group practice did their small surgery procedures while doing normal consultations. Sometimes they needed the assistance of the practice nurse who was not always available.

In two hour-long meetings, the small surgical process was described in a process flow diagram. A hazard analysis determined the probability and severity of the failure mode. The team used the national guidelines on small surgical procedures to determine a safe and practical procedure. The guidelines focused on hygiene during surgical procedures and the role of practice nurse.

After the two meetings of the PRA-team, the following conclusions were drawn:

- patients always have to make an appointment for surgical procedures;
- no surgical procedures during a normal consultation schedule;
- implement the national guidelines on hygiene and small surgery for GPs. Participants felt that PRA helped to unravel working processes and identify risks.

A focus on clinical processes (diagnosis, treatment, follow-up) will probably enhance of physicians' willingness to join programmes, while an excessive focus on the organization of healthcare could discourage health professionals from active commitment. Although serious patient safety incidents appear to have a low prevalence in primary care, the sheer volume of healthcare carried out in this setting makes it a significant problem. Building on the experience from secondary care where there has been a focus on systems, our view is that patient safety research programmes in primary care should focus on incidents in clinical processes, including underuse of effective preventive treatments and suboptimal doctor–patient communication.

Learning for and improving patient safety should be an ongoing process in every domain of healthcare. Like most improvement in quality of healthcare delivery, improving patient safety is probably a slow and incremental process.

We think that our work for the LINNEAUS collaboration identifies key areas where there needs to be a concerted attempt to address deficiencies in care where patient safety is a problem. The challenge is to identify areas where there is greatest potential for improvement taking into account issues related to both resources and time. Primary care organizations at the practice level do not have access to the resources and expertise available to larger secondary and tertiary healthcare systems in

Box 2. Prospective risk analysis (PRA) on the authorization process at a GP cooperative.

GP cooperatives deliver acute medical care during out-of-office hours. The GP cooperative where our second PRA took place offered acute primary care for approximately 500 000 people resulting in about 125 000 (telephonic, consultation or visit) contacts each year. The first contact of a patient is always by phone: to get an appointment, a visit at home or a telephone advice. About 40% of these consultations result in advice by phone by the practice nurse. The advice given has to be checked and authorized by a GP within an hour. The problem was that many of those authorizations were not done within this expected time frame and this could create an unsafe situation.

A team of a moderator, GP, and a practice assistants and a GP cooperative manager met four times for meetings of one and a half hours. They analysed the authorization process thoroughly. This analysis resulted in identifying the risks and unsafe situations in the authorization process. Possible actions to prevent these failures were discussed and assessed and one of the team members was responsible for implementing these actions.

For two failure modes, the team assessed remedial actions.

- Shifts at a GP cooperative can be very busy and pauses are not always possible so ensuring the engagement of the GP was critical. Working schemes that contained pauses and shifts of a maximum of three hours for the GP who authorizes the calls was a solution for this problem.
- The other important cause was the fact that GPs sometimes forgot to authorize at the end of their shift. It seemed important to stress the importance of authorization to the GPs. The supervising practice nurse was given the task of checking that the GP did authorize all telephonic advice consultations before leaving the GP cooperative.

order to seek improvements in patient safety and lack of evidence for interventions to improve patient safety compounds the problem. We could only provide a broad overview and generic recommendations on how to improve patient safety but it remains to be seen which interventions will be effective.

## CONCLUSION

There seems no 'magic bullet' or best method to improve patient safety. The LINNEAUS collaboration has, through the support of the Framework 7 programme developed a European network of primary care physicians and researchers, which for the first time is focusing on patient safety in primary care and developing research to address some of the identified problems. The LINNEAUS collaboration provides a clear framework for improving patient safety and crucially provides the collaborative network to help to connect improvement programmes with practicing GPs and other healthcare workers in primary care. There is room for innovative strategies as prospective methods or the use of patients in improving patient safety.

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